Individual Safety Report

3234848-6-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

RECEIVED APR 07 1999 BY:

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Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
254324 In confidence	45 yrs / [redacted]	(X)female ( )male	lbs or 75 kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr) 2/14/95

4. Date of this report (mo/day/yr) 03/30/99

5. Describe event or problem

Notification via litigation of case summaries provided by MD/co-author of lit rep(N Engl J Med 1997;337:1112-7). Info provided based on extracted data from med rec of pts hosp for APAP ingestion b/w 1/1/92&4/30/95. According to extracted data,45YO w/AML&(+)a-HCV was admitted for acute liver failure(HEPATIC FAILURE),cough(COUGH INCREASED)&FEVER. Rec did not indicate TYLENOL use PTA. Addl info rec'd 3/29/99:med rec indicate pt w/AML who rec'd 3rd cycle of chemo (2/3/95)admitted to hosp w/productive cough, CHEST PAIN, febrile,&PANCYTOPENIA. On 2/18/95,pt transferred to CCU for worsened s/s & concomitant acute LF. Pt had INC LFT's,INC NH3 level w/hepatic encephalopathy(ACUTE BRAIN SYNDROME), coagulopathy(COAGULATION DISORDER)&worsening renal function. MD's attributed to drugs(TYLENOL,others?) or infectious(HSV, CMV)etiology. Pt denied toxic ingestion or TYLENOL OD. MD d/c'd TYLENOL®#3 given prn to pt & started empiric tx w/ MUCOMYST®. Pt d/c'd 3/4/95 w/prin dx:PNEUMONIA. Rec indicate 8/17/96 pt expired. Final dx:blast crisis or relapse AML.

6. Relevant tests/laboratory data, including dates

2/3/95(PTA):AST=31,ALT=29,GGT=242,AP=100,TBili=0.3,PT=12,TP=7.8,Alb=3.4;2/6/95(PTA):Cr=0.7,WBC=8,H/H=9.4/29.2,Plt=278; 2/14/95:WBC=less than 0.5,H/H=8.3/24.2,Plt=less than 3,AST=34,AP=165,TBili=0.6,TP=8.3,Alb=4.1;2/16/95:CXR= (See sec B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

AML M2 dx'd(8/94),IVDA not in 4yrs,HIV(-),Hep(-),tob 1-2ppdx 10y,ETOH none in 3yrs;2/22/95 note indicates(+) test for HCV antibody. IgM pending. (Sec B6 cont)RLL infil,2/17/95:BC:no fungus,WBC=0.3,Plt=17,NA=131,CO2=19,Cr=1.7,glu=142,PT=20.2, NH3=110,AST=9310,ALT=3120,GGT=379,AP=142,TBili=5.2,TP=6.2, Alb=2.7;2/18/95:APAP level=5,gluc=208;2/20/95: (See sec C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Regular Strength TYLENOL
#2 TYLENOL #3

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1-2 po q4-6h prn in hosp	#1 2/15/95 & 2/16/95;once ea dy
#2 1-2 po q4-6h prn in hosp	#2 2/14/95-2/17/95

4. Diagnosis for use (indication)

#1 pain
#2 pain

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

Ortho Novum 777,3rd cycle HIDAC comp'd 2/3/95(Sec B7cont)RLL BL:no AFB or fungus isolated,no pneumocystis seen,WBC=2.4,H/H=7/20,Plt=25,Na=146,Cl=112,CO2=21,Cr=1,BUN=18,glu=305,Phos=2.3,PT=16.8,AST=455,ALT=1429,GGT=406,AP=151,TBili=4,Alb=2.5

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

DSS APR 08 1999 ADVERSE EVENT REPORTING SYSTEM

2. Phone number 215-273-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr) 03/29/99

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)

LIVER FAILURE, COUGH INCREASED, FEVER, PAIN CHEST, PANCYTOPENIA, BRAIN SYND ACUT, COAGULATION DIS, PNEUMONIA

9. Mfr. report number 0905688A

E. Initial reporter

1. Name, address & phone #

[redacted] MD [redacted]
[redacted] Medical Ctr
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.